K092405
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510(k) Summary

General information

The general information for the MammoSite ML is included in the table below:

Submitters name and address:	Hologic, Inc. 250 Campus Drive Marlborough, MA 01752
Submitters phone and fax numbers:	Telephone: (508) 263-8912 Fax: (508) 263-2403
Name of contact person:	Jennifer L. Sullivan *Regulatory Affairs Specialist*
Trade name:	MammoSite Multi Lumen Radiation Therapy System (RTS)
Common name:	Remote-controlled radionuclide applicator system
Classification name:	System, applicator, radionuclide, remote controlled (per 21 CFR 892.5700)
Date summary was prepared:	August 5, 2009

Predicate devices

The MammoSite ML is substantially equivalent to the following cleared devices:

Name	Manufacturer	510(k) Number
MammoSite Radiation Therapy System (RTS)	Hologic, Inc.	K041929
SAVI Applicator Kit	Cianna Medical	K081677

Indications for use

The MammoSite ML is intended to provide brachytherapy when the physician chooses to deliver intracavitary radiation to the surgical margins following lumpectomy for breast cancer.

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510(k) Summary, Continued

Device description	The MammoSite ML applicator is used to position tissue and the radioactive source during breast brachytherapy treatments. It consists of a multi-lumen polyurethane catheter with an inflatable balloon assembly at its distal end.
Technological characteristics	The MammoSite ML has the same intended use, similar technological characteristics, and similar materials/dimensions of the predicate devices. The indication for use is the same as the predicate devices. Testing indicates that the MammoSite ML is substantially equivalent to the legally marketed predicate devices. All MammoSite devices provide a means of delivering a radiation therapy in a tumor or tumor cavity. The MammoSite positions the radioactive source for radiation therapy and utilizes a 192Ir seed as the radiation source with similar dosimetric properties.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Ms. Jennifer Sullivan
Regulatory Affairs Specialist
Hologic, Inc.
250 Campus Drive
MARLBOROUGH MA 01752

AUG 2 7 2009

Re: K092405
Trade/Device Name: MammoSite Multi Lumen (ML) Radiation Therapy System (RTS)
Regulation Number: CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: August 5, 2009
Received: August 6, 2009

Dear Ms. Sullivan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of the MammoSite ML Radiation Therapy System (RTS) as a replacement for whole breast irradiation in the treatment of breast cancer has not been established.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (301) 796-5500. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 301-796-5760. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known)	K092405
Device name	MammoSite Multi Lumen (ML) Radiation Therapy System (RTS)
Indications for use	The MammoSite ML is intended to provide brachytherapy when the physician chooses to deliver intracavitary radiation to the surgical margins following lumpectomy for breast cancer.

Prescription Use ____X____ AND/ OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092405